CLAIMS

We claim:

1. A composite microsphere system comprising
poly(D,L-lactide-co-glycolide) (PLGA);
poly(acryloyl hydroxyethyl starch) (AcHES); and
a pharmaceutically effective amount of a biologically active compound;
wherein the biologically active compound is a polypeptide having a molecular weight of about 200 to about 160,000 Daltons.

2. The composite microsphere system of claim 1, wherein the biologically active compound is selected from the group consisting of an insulin, an interferon, a luteinizing hormone-releasing hormone (LHRH) analog, a somatostatin and/or somatostatin derivative, a calicitonin, a parathyroid hormone (PTH), a bone morphogenic protein (BMP), an erythropoietin (EPO), an epidermal growth factor (EGF) and a growth hormone.

3. A drug formulation comprising a composite microsphere system comprising
poly(D,L-lactide-co-glycolide) (PLGA);
poly(acryloyl hydroxyethyl starch) (AcHES); and
a pharmaceutically effective amount of a biologically active compound;
wherein the biologically active compound is selected from the group consisting of an insulin, an interferon, a luteinizing hormone-releasing hormone (LHRH) analog, a somatostatin and/or somatostatin derivative, a calicitonin, a parathyroid hormone (PTH), a bone morphogenic protein (BMP), an erythropoietin (EPO), an epidermal growth factor (EGF) or a growth hormone; and
a pharmaceutically acceptable vehicle.

4. A method for the sustained release delivery of a therapeutic compound to a subject comprising:

administering to the subject a composite microsphere system comprising

poly(D,L-lactide-co-glycolide) (PLGA);

poly(acryloyl hydroxyethyl starch) (AcHES); and

a pharmaceutically effective amount of a biologically active compound;

wherein the biologically active compound is selected from the group consisting of an insulin, an interferon, a luteinizing hormone-releasing hormone (LHRH) analog, a somatostatin and/or somatostatin derivative, a calicitonin, a parathyroid hormone (PTH), a bone morphogenic protein (BMP), an erythropoietin (EPO), an epidermal growth factor (EGF) or a growth hormone.

5. The method of claim 4, wherein the subject is suffering from a condition which can be treated by the administration of a biologically active compound selected from the group consisting of an insulin, an interferon, a luteinizing hormone-releasing hormone (LHRH) analog, a somatostatin and/or somatostatin derivative, a calicitonin, a parathyroid hormone (PTH), a bone morphogenic protein (BMP), an erythropoietin (EPO), an epidermal growth factor (EGF) or a growth hormone.

6. The method of claim 4, wherein the subject is a vertebrate or an invertebrate organism.

7. The method of claim 4, wherein the subject is a canine, a feline, an ovine, a primate, an equine, a porcine, a caprine, a camelid, an avian, a bovine, an amphibian, a fish, or a murine organism.

8. The method of claim 4, wherein the primate is a human.

9. The method according to claim 4, wherein the drug is administered intramuscularly.

10. The method of claim 4, wherein the microspheres are in a pharmaceutically acceptable vehicle.

11. The method of claim 4, wherein the microspheres are administered topically.

12. The method of claim 11, wherein the topical administration is via inhalation or nasal administration.

13. The method of claim 4, wherein the microspheres are administered parenterally.

14. A method of preparing a composite microsphere system of claim 2, comprising

incorporating a biologically active ingredient selected from the group consisting of an insulin, an interferon, a luteinizing hormone-releasing hormone (LHRH) analog, a somatostatin and/or somatostatin derivative, a calicitonin, a parathyroid hormone (PTH), a bone morphogenic protein (BMP), an erythropoietin (EPO), an epidermal growth factor (EGF) or a growth hormone into AcHES hydrogel microparticles; and

encapsulating the resulting AcHES hydrogel microparticles containing the biologically active ingredient into a PLGA matrix.

15. The method of claim 14, wherein the AcHES hydrogel microparticles containing the biologically active ingredient are incorporated into the PLGA matrix

using a process selected from the group consisting of solvent extraction, solvent evaporation, spray drying, freeze drying and a combination thereof.